JUN - 3 2008

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM:

OrthoPediatrics, Corp.
210 N. Buffalo Street
Warsaw, Indiana 46580
Establishment Registration No.: 9102640

510(K) CONTACT:

Gary Barnett
VP-Regulatory & Operations
Tel: (574) 268-6379
Fax: (574) 269-3692

TRADE NAME: OrthoPediatrics PediFlex ™ Flexible Nail System

COMMON NAME: Intramedullary Elastic Nail

CLASSIFICATION: 21 CFR 888.3040 Smooth or threaded metallic bone fastener: Class II per 21 CFR §888.3040

DEVICE PRODUCT CODE(S): HTY

SUBSTANTIALLY EQUIVALENT DEVICES:

Synthes EIN (K971783), Synthes (USA)

Nancy Nail (K032687), DePuy ACE, Inc.

DEVICE DESCRIPTION:

The nail is available in 2.0, 2.5, 3.0, 3.5, and 4.0 mm diameters, each 440 mm long, which can be cut to length intra-operatively. The PediFlex has a curved, tapered tip to facilitate insertion. This is a single use device intended for temporary implantation. It is intended to be removed once the bone has healed.

- Materials: The devices are manufactured from Ti-6Al-4V which meets ASTM F136, and ISO-5832 standards.
- Function: The system functions to provide immediate stability and temporary fixation during the natural healing process.

INDICATIONS FOR USE:

The PediFlex (Flexible) Nail System is intended for fixation of diaphyseal fractures of long bones where the medullary canal is narrow or flexibility of the implant is required. This includes upper extremity fractures in all patients and

lower extremity fractures in pediatric or small stature patients. In pediatric patients, the flexibility of the nail allows it to be inserted at a point that does not disturb or disrupt the growth plate.

BASIS FOR SUBSTANTIAL EQUIVALENCE:

OrthoPediatrics believes that this system is substantially equivalent to the legally marketed predicate devices based on similarities in design, materials, and indications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 2008

OrthoPediatrics, Corporation
% Mr. Gary Barnett
Vice President, Regulatory & Quality
210 N. Buffalo Street
Warsaw, Indiana 46580

Re: K081097
Trade/Device Name: OrthoPediatrics PediFlex™ Flexible Nail System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulation Class: Class II
Product Code: HTY
Dated: April 16, 2008
Received: April 17, 2008

Dear Mr. Barnett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240)- 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240)- 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K081097

Device Name: OrthoPediatrics PediFlex ™ Flexible Nail System

The PediFlex Flexible Nail System is intended for fixation of diaphyseal fractures of long bones where the medullary canal is narrow or flexibility of the implant is required. This includes upper extremity fractures in all patients and lower extremity fractures in pediatric or small stature patients. In pediatric patients, the flexibility of the nail allows it to be inserted at a point that does not disturb or disrupt the growth plate.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081097